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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,117

04/02/2004

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EXAMINER

BOESEN, AGNIESZKA

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/817,117	<b>Applicant(s)</b> CARBONELL ET AL.	
	<b>Examiner</b> Agnieszka Boesen	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8 and 34-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Office Action</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

This Non-Final Office Action is responsive to the communication received March 29, 2006.

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Agnieszka Boesen Art Unit 1648.

#### ***Election/Restrictions***

Applicant's election with traverse of group I, claims 1-6, and 9-33, and the species: PrPSc, the Polymethylacrylate (TOYOPEARL™ Amino 650), human, and blood derived sample is acknowledged.

Applicant argues that no adequate reasons and/or examples were provided to support the conclusion of patentable distinctiveness between Applicant's claimed subject matter. Applicant submits that the statement regarding the serious burden on the examiner was lacking in the restriction requirement of December 28, 2005 and thus the restriction is improper. Applicant also argues that election of species requirement is improper. Applicant's arguments have been fully considered but they are not persuasive. Since the matrixes of different structures have different effects on the prion protein, a different search would be required to find literature about different complexes between the prion protein and its binding material. Searching all claimed forms of prion molecules, all polymeric binding materials all animal species, and all types of

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samples would require different searches because the claimed species are different structurally and functionally. Searching all types of species together would require separate searches and the literature regarding one species would not reveal the information about another species. Thus, searching all inventions together would be a serious burden to the Examiner. For the reasons set forth above the restriction requirement is deemed proper and made FINAL.

Claims 7, 8, and 34-39 are withdrawn because they are drawn to the non-elected invention. Claims 1-6, and 9-33 are currently examined.

#### ***Information Disclosure Statement***

The Information Disclosure Statement received March 13, 2006 has been considered and is attached to this Office Action

#### ***Specification***

The use of the trademarks TOYOPEARL<sup>TM</sup>, TSK-GEL<sup>TM</sup>, and FRACTOGEL<sup>TM</sup> has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 15 contain the trademark/trade names FRACTOGEL™ EMD, TOYOPEARL™, and TSK-GEL™, and TOYOPEARL™ AMINO 650. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the polymer matrix and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1-6, and 9-33 are rejected under 35 USC 102(b) as being anticipated by Foster et al., (2000, Vox Sanguinis Vol. 78, p. 86-95) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS).**

Claims are drawn to a method of forming and detecting a complex between a prion protein in a sample and prion protein binding material. The prion protein binding material comprises a polymer matrix Toyopearl™ amino 650. The sample containing the prion molecule is a blood-derived sample. The prion protein binding material further comprises a spacer connecting the polymer matrix and a functional group.

Foster et al., disclose a method of removal of prion protein from human plasma using Toyopearl amino 650M (see the entire document, particularly the abstract and Table 2 on page 92). It is noted that DEAE-Toyopearl™ 650M is the same as Toyopearl™ amino 650 and Toyopearl™ AF amino 650 M. DEAE stands for diethylaminoethyl (a limitation recited in claim 11), which is an amine group, which is a functional group that is bound to the polymer matrix. Toyopearl™ used by Foster et al., is the same Toyopearl™ recited in the instant claims. It is noted that the limitation recited in claims 31-33 is an inherent property of the Toyopearl™ AF amino 650 M product as evidenced by Data Sheet and the manual for the product (see Affinity Chromatography manual Figure 6).

It is also noted that limitation of forming and detecting a complex between a prion protein in a sample and prion protein binding material are encompassed by the method of removal of prion protein disclosed by Foster et al.

By this disclosure Foster et al., anticipate the subject matter of the instant claims.

**Claims 1-6, and 9-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammond et al., (U.S. 6,750,025).**

As indicated above, the instant claims read on methods of detecting prions in blood-derived samples comprising contacting the prions with the prion binding material. The prion binding material is a Toyopearl amino 650, a polymer matrix bound to an amine group.

Hammond et al., identify a ligand for prions (see claim 1). The reference also discloses that the identified ligand may be used either for the detection of prions, or for the removal of prions from a sample (see, column 2, lines 50-63). As means for carrying out the invention, the reference teaches that the ligand may be attached to the affinity column formed on a resin, including on Toyopearl resins (see, column 5, lines 6-17). The reference further identifies a Toyopearl amino 650 M resin as a Toyopearl resin (column 10, lines 44-46).

Based on this disclosure Hammond anticipates the rejected claims.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in

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accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-6, and 9-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruisner (US Patent 6,221,614 B1) in view of Kragten et al., (1998, J Biol Chem 273: 5821-28) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS).**

Claims are drawn to a method of forming and detecting a complex between a prion protein in a sample and prion protein binding material. The prion protein binding material comprises a polymer matrix Toyopearl amino 650. The sample containing the prion molecule is a blood-derived sample. The prion protein binding material further comprises a spacer connecting the polymer matrix and a functional group.



Prusiner et al. teach a method for detection and removal of prions from blood plasma comprising forming a complex between the prion molecule and a complexing agent (see the entire document, particularly claim 1 and claim 6, column 2 lines 53-67, and column 8 lines 43-56). An example of the complexing agent taught by Prusiner et al. is a polymer matrix coupled to a hydrophobic ligand (see column 12, lines 30-55). Although the Prusiner reference provides several examples of purification techniques, and complexing agents, the reference does not specifically teach the use of a polymer matrix, such as Toyopearl amino 650.

Kragten et al., teach a method for affinity precipitation of protein using polymer matrix (Toyopearl AF amino 650 M resin) (see e.g., page 5822, 3<sup>rd</sup> paragraph under Experimental Procedures). The teachings of this reference demonstrate that the polymer matrix is a known substrate for use in affinity-based separation of proteins from samples.

One of the ordinary skill in the art at the time the invention was made would have been motivated to use Toyopearl™ AF amino 650 M resin to form complexes with prion molecules and subsequently detect the formed complexes, because Prusiner et al., suggests to use polymer matrices for detection of prion molecules and because Toyopearl™ AF amino 650 M is a commonly used substrate for protein purification as taught by Kragten et al. and as evidenced by Data Sheet for Toyopearl™ AF amino 650 M product.

One of the ordinary skill in the art would have had a reasonable expectation of success to use Toyopearl AF amino 650 M for detection of prion molecules as taught by Kragten et al., and Prusiner et al. One would have had a reasonable expectation of success that Toyopearl™ amino 650 would have worked in Prusiner's method because Prusiner suggests polymer matrices.

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It is noted that the limitation recited in claims 31-33 is an inherent property of the Toyopearl™ AF amino 650 M product as evidenced by Data Sheet and the manual for the product (see Affinity Chromatography manual Figure 6).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-6 and 8-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/962, 670.**

Claims 1-6 and 8-33 of the instant application are drawn to a method of forming and detecting a complex between a prion protein and prion protein binding material. Claims 1-20 of the reference application are drawn to a method of detecting and separating prion protein from a sample comprising contacting the sample with a polymeric prion protein binding material. The prion binding material both the instant and the reference application is a Toyopearl™ amino 650, a polymer matrix bound to an amine group.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are generic to the present claims. The limitations of the present claims are inherent to the copending claims (i.e. forming and detecting a complex between a prion protein and a prion protein binding material. The present claims are therefore obvious variations of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035.

The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB  
Agnieszka Boesen, Ph.D.  
Examiner

June 7, 2006

Stacy B. Chen 6/7/06  
Stacy B. Chen  
Primary Examiner